

MAY - 8 2001

16010595

510(k) Summary

Submission

Submitted by: dj Orthopedics, LLC
2985 Scott Street
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Application Preparator: Alaron Technologies, LLC
(contact for additional information) Jamal Rushdy
990 Park Center Drive, Suite H
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Date of preparation: February 16, 2001

Device

Common Name: Interference Screw
Trade Name: Dj Orthopedics Interference Screw
Classification Name: NDJ, Screw, Fixation, Bone, Non-Spinal, Metallic
Predicate Device: Smith & Nephew RCI/SIS Screws, K945687

Description and Intended Use

Dj Orthopedics Interference Screws are designed to facilitate cruciate ligament reconstruction surgeries. The screws are utilized to secure soft tissue grafts such as bone-patellar tendon-bone or hamstring grafts to prepared bone tunnels in ACL reconstruction surgeries.

Intended Use:

Dj Orthopedics Interference Screws are intended for use in the fixation of ligament and/or tendon grafts in cruciate ligament reconstruction surgeries.

Technological Characteristics

Feature	Dj Orthopedics Interference Screws	Smith & Nephew RCI/SIS Screws
Indications	Fixation of ligament and/or tendon grafts in cruciate ligament reconstruction surgeries	Interference fixation of patellar bone-tendon-bone or hamstring grafts in anterior or posterior cruciate ligament reconstruction
Sizing	7-10mm diameters, 20-50mm lengths	7-9mm diameters, 20-50mm lengths
Material	Surgical Grade Titanium, Ti6Al4V	Surgical Grade Titanium

Conclusion

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 8 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jamal D. Rushdy
Alaron Technologies, LLC
990 Park Center Drive, Suite H
Vista, California 92083

Re: K010595

Trade/Device Name: Dj Orthopedics Interference Screw
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HWC
Dated: February 16, 2001
Received: February 28, 2001

Dear Mr. Rushdy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

Page 2 - Mr. Jamal D. Rushdy

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Devices Evaluation

Center for Devices and

Radiological Devices

Enclosure

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: dj Orthopedics, LLC

510(k) Number (if known): K 010595

Device Name: Dj Orthopedics Interference Screw

Indications For Use:

Dj Orthopedics Interference Screws are intended for use in the fixation of ligament and/or tendon grafts in cruciate ligament reconstruction surgeries.

B. M. Sullivan for CDRH
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010595

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)